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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,816	08/25/2003	Joseph P. Reo	00995.US1	2357

7590 07/28/2005

PHARMACIA CORPORATION
Global Patent Department
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EXAMINER	
GEMBEH, SHIRLEY V	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 07/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/647,816	REO ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Objections

The use of trademarks in the specification has been noted in this application. They should be capitalized wherever they appears and be accompanied by the generic terminology. Preferably applicant should list the ingredients contained in the trademark for example SWEET AM™ on page 6 of specification §0040 lines 2, 9-11) at the time the invention was made. Note that over time the trademark can change and will not enable one skill in the art to carry out the same experiments

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The recitation in the specification "http//.www.ortho-mcneil.com/products/pi/Lg%20PI.pdf" is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arneric et al., US 2003/0060513 A1, Hawley et al., US 2003/0199582 A1 in view of Pediatric Pharmacotherapy A Monthly News letter for Health Care Professionals Childrens' Medical Center at the University of Virginia Vol 2 No. 9 September 1996 and Gage et al., US 5922914.

Arneric et al., teach a pharmaceutical composition (abstract), tolterodine (page 2 §0022, line 4) pharmaceutically acceptable salt (page 4 §0065 line 17+) in an orally

deliverable liquid syrup or elixir (page 5 §0068), therapeutic effective concentration 0.05-5 mg (page 4 §0059, line 3), wherein the tolterodine related compound is hydroxytolterodine and tolterodine taught at (page 2 §0022, line 4). Arneric also teach salts of tolterodine selected from benzoate, maleate, tartate and the likes (page 4 §0065, lines 1+), and the salt tolterodine is tolterodine tartate (page 2 §0022, line 7), where the concentration of tolterodine is about 1 mg at §0059, line 3.

Arneric et al., also teach sweetening agent such as sucrose §0068 page 5 lines 1+ and a flavoring agent to treat overactive bladder §0072, lines 1+.,administered 1 to 2 times daily taught at §0082, lines 1+.

Arneric did not teach of the composition having a pH of about 2-6, and the antimicrobial agent. Arneric et al., also teach that such pharmaceutical compositions can be prepared by methods and contain excipients which are well known in the art (§0066 lines4+) therefore adding an antimicrobial agent sodium benzoate (an excipient) would have been obvious to the ordinary skilled artisan.

Hawley et al., teach salts of tolterodine §0039, at pH 6.0, §0034, to treat urinary disorder §0038, such as overactive urinary bladder §0047, in a liquid form §0041, an effective amount 0.2mg/0.2 ml §0051 lines 7+ and §00521+ and buffers §0056.

Pediatric pharmacotherapy teaches antimicrobial addition to medication is to prolong shelf life and maintain sterility. One common antimicrobial agent used is sodium benzoate as disclosed by applicant. (See page 1 of reference).

Gage et al., teach tolterodine from its acid salts (hydrochloride etc), and the addition of citric acid column 4 lines 28+.

One of ordinary skill in the art at the time the invention was made would have combined the teachings of the cited prior art above to formulate a drug, tolterodine tartate suspension that contains an antimicrobial agent. The foregoing suspension composition would have been used to treat bladder related disease. With bladder /urinary related disease bacterial infection to the liver is not ruled out, therefore, would have been obvious to the ordinary skilled artisan at the time the claimed invention was made to include an antimicrobial agent (sodium benzoate) to the composition, not only for longer shelf life, sterility but also as a measure for any bacteria developed by patient.

One of ordinary skill in the art would have known that the pH of the composition would be acidic, for example to form the acid salt as taught by Gage concentrated hydrochloric acid is added. It is therefore obvious to one of ordinary skill in the art that the product have to have been very acidic ranging from a pH of 2 to 6.

Therefore one of ordinary skill in the art would have expected a successful result using tolterodine and its related compound to treat overactive bladder. The art recorgnizes tolterodine for treating urinary/bladder associated disease or disorder.

Further, one of ordinary skill in the art would have been motivated to combine the teachings of the above cited prior art to administer tolterodine (oral liquid form) in a pharmaceutical acceptable salt as taught. Thus the claims are deemed prima facia obvious over the prior art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00 Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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